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[0001] The invention relates to a breathing mask to the supply of a breathing gas to an patient as well as a method to the production the same.

[0002] Breathing masks that initially mentioned type find in particular application in the range of the sleep medicine. Over such breathing masks the patient a breathing gas ambient air can become a bottom pre-determined overpressure supplied. Thereby on physiological comparatively good compatible manner a pneumatic Schienung of the upper respiratory system achieved whereby possible Obstruktionen in this range on advantageous manner one will prevent can.

[0003] The masques applied in the range of the sleep medicine daily become approx. with the treating a patient in the frame of a CPAP Schlaftherapie. 6 to 8 hours carried. With the application of the so far known masques the problem exists with many patients that the desired sealing effect of the masque only bottom comparatively large mask retaining forces achieved can become and here the inertial comfort possibly. significant impaired becomes.

[0004] The invention is the basis the object to create a breathing mask to the supply of a breathing gas bottom overpressure by an high inertial comfort is characterised and by which an high sealing degree on reliable manner ensured is.

[0005] This object becomes in each case according to invention for itself by a breathing mask with at least in the independent claims and indicated features the dissolved.

[0006] By it will reach on advantageous manner possible during a small surface pressure in the range of the face contact zone a continuous intimate plant of the inner sealing area without the risk insists that smaller changes of position of the breathing mask opposite the face of the patient to significant changes of the contact pressures to lead. In advantageous manner is also opposite conventional breathing masks a better compatibility to the individual face forms of the respective patients given.

[0007] One both regarding an high inertial comfort as well as bottom technical aspects favourable embodiment of the invention is given by the fact that the mask basis body from an elastomeric material is formed. Regarding an high physiological compatibility as well as good sterilization barness the mask basis body and the front edition element are preferably formed from a silicone material. Also the sealing means are preferably formed from a silicone material.

[0008] A particularly loadable and essentially gap-free coupling of mask body and sealing means is particularly in accordance with one preferable embodiment of the invention given by the fact that mask basis body is moulded on to the sealing means. Alternative one in addition is it also possible to mould on the sealing means to the mask basis body if the material a sufficient temperature resistance used to the formation of the mask body exhibits.

[0009] Regarding a particularly high inertial comfort as well as regarding an high sealing effect favourable embodiment of the invention is given by the fact that a stiffening element is provided, which lends a predetermined shape to the mask basis body and/or the sealing means. This stiffening element is preferably formed from bottom heat input a deformable material and maintains after cooling off on room temperature it the imparted shape of bottom if necessary elastic deformation to a large extent.

[0010] A particularly individual adaptation of the breathing mask to the head form of the patient becomes particularly in accordance with one preferable embodiment of the invention achieved by the fact that itself the stiffening element into the front edition element inside extended.

[0011] In the mask basis body and/or the front edition element a receiving portion is preferably formed, to the receptacle of the reinforcement element. This receiving portion can be by a complementary recess formed to the cross section of the reinforcement element formed. Preferably the stiffening element narrow seated in this recess received, bedarfsweise is bonded.

[0012] At the front edition element a coupling mechanism is preferably provided, to the terminal of a mask retaining strap.

[0013] An embodiment of the invention favourable regarding one particularly even distribution of the mask retaining forces is given by the fact that the sealing means exhibit a pad organ from an elastomeric wall material the limited are. The pad organ extended itself preferably in the type of a hose pad along the mask edition range. At the pad organ preferably an integral sealing lip formed with the pad organ is the provided itself inward extended of the mask external area.

[0014] In particular the combination from hose pad and integral front edition element, if necessary. with reinforcement insert, leads to a breathing mask, which is characterised with high tightness by an exceptionally high inertial comfort.

[0015] Regarding a particularly simple cleaning possibility an interior transient area between the sealing lip and the pad

organ is preferably rounded formed.

[0016] The sealing means to the seal of the mask basis body can exhibit alternative to the described pad body also an organ formed from a gel-like cured elastomeric material, whereby the elastomeric elastomeric portion portion is preferably formed with a skin layer coated from an elastomeric material is. Thereby on surprising effective manner of an adverse formation of pleats one prevents. The skin layer preferably is from high crosslinked silicone rubber material a formed.

[0017] The skin layer mentioned can become on technically advantageous manner by job of a thin silicone material layer on a corresponding form space section of a forming tool formed, whereby the late gel-like hardening silicone material into the corresponding prepared, remaining form space section injected is and here an intimate connection with the skin section becomes achieved.

[0018] If necessary, also independent of the preceding described measures is an embodiment of the breathing mask with a mask basis body a mask interior of the limited, an inhaled gas inlet section, favourable in accordance with an other Erfindungsgedanken in particular bottom technical aspects, to the lead from breathing gas to the mask interior, and resilient sealing means to the seal of the mask basis body by the fact given that the mask basis body from a thermoplastic plastic material formed and to the sealing means is moulded on.

[0019] Further it is possible in advantageous manner to train the sealing means in such a manner that this covers along a mask edition range extending air cushion element and that an approaching or a splice of the air cushion element spread at least in sections from a receiving portion of the mask basis body is.

[0020] A cushion member particularly favourable regarding an high inertial comfort becomes in particular also independent of the preceding described measures achieved by the fact that the sealing means exhibit a sealing rim element from a silicone material with high degree of crosslinking the made are, and that is coupled to this sealing rim element a pad body, which is made from a silicone material of low degree of crosslinking. Preferably the pad body is at least in the range of the face bearing surface with an elastomeric skin coated.

[0021] In particular with the embodiment of the pad element as air cushions the sealing means become particularly by a hose pad formed from an elastomeric material formed whereby wall sections of the hose pad in such a manner defined thick and thin walled formed are in accordance with one preferable embodiment of the invention that in pre-determined zones joint zones develop.

[0022] Preferably an inward directed circumferential sealing rim element is integral with the pad body formed with this embodiment.

[0023] Bottom technical aspects becomes the initially indicated object also dissolved by a method the production of a breathing mask, with which in the frame of a first silicone injecting procedure silicone material becomes into a form space section injected that complementary mask sealing means formed is, whereby in the frame of a subsequent method step a mask-body-lateral connecting region first released from form and subsequent becomes in complementary form space section introduced formed to a mask body, and only a subsequent plastic material becomes into that, the mask body complementary mould space injected.

[0024] Other details and features of the invention result from the subsequent description of several preferred embodiments in connection with the drawing. Show:

Fig. 1a: a simplified perspective view of a breathing mask with integrated front edition element;

Fig. 1b: a simplified sectional view by a preferable embodiment of an air cushion range, like it for example with the breathing mask in accordance with. Fig. 1 A application to find can, with releasable mounted binding strakes;

Fig. 1K: a simplified detail view to the explanation of a fastening part for the coupling of a strut arrangement with the breathing mask;

Fig. 1d: a simplified perspective view to the explanation of the structure of a front edition element, which is integral formed with the mask basis body from an elastomeric material;

Fig. 1e: a sketch to the explanation of the shape of the mask upholstery for the range of the nose back of an patient;

Fig. 2: a perspective view of a reinforcement element for a breathing mask, itself into the front edition range inside the extended;

Fig. 3a: an other embodiment of a reinforcement element for a mask basis body, which is made from a wire material with essentially circle-cylindrical cross section here;

Fig. 3b: an isometric detail view, by the sealing rim range of a mask element in the range of the nose back also to it mounted stiffening element essentially in accordance with. Fig. 3a;

Fig. 4: a simplified sectional view by the sealing rim range of a breathing mask with a gel pad body as well as immediate adjacent disposed stiffening element;

Fig. 5: a simplified sectional view by a sealing rim range with moulded on mask basis body;

Fig. 6: a simplified sectional view to the explanation of a sealing rim range with integrated hose pad as well as mask-basis-body-laterally practice-grasped interface;

Fig. 7: a simplified sectional view by a sealing rim structure with a gel body its moulded on to a main sealing rim the patient directed exterior with an elastomeric skin layer coated is;

Fig. 8: a simplified sectional view by a sealing rim structure with formed thin walled wall zones to the formation defined joint zones, defined therein;

[0025] Fig. 1 shows a first preferable embodiment of a breathing mask, which exhibits a mask basis body 1 with an integral Stimauflegeelement 2 formed thereby. With the illustrated embodiment the mask basis body 1 and the Stimauflegeelement 2 from an elastomeric material are, in particular silicone rubber formed. The mask basis body 1 is by a circumferential stiffening element 3 amplified. With the illustrated embodiment the stiffening element 3 consists of a plastic material, which became tuned regarding its spatial shape in the heated state individual on the patients. The stiffening element 3 is in here only andeutungsweise represented circumferential groove at the mask basis body 1 a fixed.

[0026] The mask basis body 1 exhibits further integral with this formed sealing rim element 4, which here a circumferential hose pad (see. Fig. 1 b) covers. The sealing rim element 4 and the mask basis body 1 are likewise

integrally formed, so that between the sealing rim element 4 and the mask basis body no gap regions formed are.

[0027] In the mask basis body 1 further outlet ports are 5, 6 formed, over which permanent bottom overpressure standing gas can escape from the interior region of the masque outward. The outlet ports 5, 6 are here by small slots formed formed into the mask basis body 1. With that illustrated embodiment are the slots from each other separate by thin, likewise integral bars formed with the mask basis body 1 here. Alternative one for this it is also possible, a screen structure, which exhibits a defined cross-sectional flow to begin into a corresponding 1 receiving opening formed in the mask basis body releasable einzuklippen in particular. The arrangement of the outlet ports 5, 6 is in such a manner met with the breathing mask shown that inside the breathing mask no significant perceptible air flows arise on the part of the patient. The cross-sectional flow, that the front edition element 2 adjacent outlet ports 6 is with the illustrated embodiment large dimensioned, as the cross-sectional flow of the discharge openings 5 planned within the nose point range. The relative importance is in such a manner fixed that approx. 2/3 of the effluent air by those the front range adjacent outlet ports 6 and the remaining third by the front outlet ports 5 divert. Thereby an optimal exchange of the spent breathing air becomes achieved with small draft features.

[0028] The front edition element 2 is in such a manner formed that this rests upon wide and bottom even surface pressure on the front range of the patient. The front edition element 2 is provided with holding members 7, at which a corresponding coupling section of a mask mounting plate, in particular a strut arrangement or a retaining cap is attachable. A preferable embodiment of these holding members 7 is in Fig. 1K of shown. The mask basis body 1 is in such a manner formed that the transition region between the mask basis body and the sealing rim element essentially exhibits one the face form of the patient the subsequent high process. In particular the mask basis body is in the range of the nose back of the patient such a drawn formed that the sealing rim element - as in Fig. 1 e indicated - saddle-like over the nose back of the patient guided will can.

[0029] The sealing rim element 4 points in accordance with, a preferable embodiment of the invention a cross section up, that essentially the illustration in accordance with, Fig. 1b corresponds. The sealing rim element 4 represented here covers a hose pad body 8 and a here integral face sealing rim 9 formed with the hose body 8. The face sealing rim 9 refers to itself here in the range of the coupling place with the hose pad body 8 one comparatively large thickness  $t$  up and tapered increased to a point range  $s$ . In a transition region formed between the pad body 8 and the root portion of the face sealing rim 9 here a curvature is 10 formed, whereby this intermediate region formed between the face sealing rim 9 and the hose pad body 8 can be cleaned improved.

[0030] The hose pad body 8 is in the range of the outside hose wall 8a thick walled formed, as in the range of the mask-interior lateral hose wall 8b. The transition between the face lip 9 and the outside hose pad wall 8a is in such a manner corrugated that the spatial course of the face lip 9 as well as the hose pad body can become 8 significantly by the stiffening element 3 affected. The stiffening element 3 exhibits here an essentially rectangular cross section and is in a recess 11 received, which is the immediate hose pad body 8 adjacent disposed. With that illustrated embodiment are here the hose pad body 8 and itself the mask basis body subsequent to it 1 integral from the same elastomeric material formed. The recess 11 is over a slot range 12 to the outside of the breathing mask open, so that the stiffening element can become 3 bedarfsweise 1 remote of the mask basis body. The face sealing rim 9 and the hose pad body 8 are in such a manner disposed that the pressing force of the face sealing rim becomes 9 8 amplified still other by the hose pad body, if the mask basis body becomes 1 with a pre-determined contact pressure against the face of the patient urged.

[0031] This pre-determined contact pressure becomes preferably generated over a strut arrangement, which exhibits at least a webbing led around around the back of the head range of an patient. This webbing can over corresponding end pieces, and/or. Coupling organs with the breathing mask over the holding members 7 coupled already specified become in a simple manner. These holding members 7 can - as in Fig. 1K of shown - integral with the mask basis body 1, and/or. with its front edition element 2, formed its. In present cases exhibit the holding members a shaft portion 13 and a ball section 14 formed to it. The diameter of the head portion 14 is larger as the diameters of the shaft portion 13. Such holding members are preferably disposed at several locations of the breathing mask 1, in particular also in the front region of the mask basis body 1 - like indicated -.

[0032] As from Fig. 1 D comes out, is with the represented breathing mask the front edition element 2 such elongated formed that an even distribution of the tracking forces results. The front edition element 2 is 1 coupled over a neck portion with the mask basis body. The mask basis body 1, the neck portion 15 and the front edition element 2 are here integrally formed. By the neck portion 15 through extended itself an inhaled gas channel 16, which in one - likewise with the front edition element 2 formed terminal portion 17 flows. The inner diameter of the terminal portion 17 is in such a manner formed that a corresponding connection structure of an inhaled gas hose of immediate into the terminal portion 17 inserted can become. In the range of the terminal portion 17 are also the preceding already bottom reference on Fig. 1a explained outlet ports 6 provided, over which a pre-determined gas flow can escape outward. The front edition element 2 exhibits two wing portions 18 with the illustrated embodiment, by which the Stimauflegeelement 2 is still continued to reinforce, and besides becomes the transmitted uniform over the holding members 7 introduced pulling forces. Also the wing portions 18 are formed with the illustrated embodiment integral with the mask basis body, the neck portion 15 and the front edition element 2 from an elastomeric material. By corresponding shape of section of the wing portions the deformation behavior of the Stimauflegeelementes can become targeted affected.

[0033] In Fig. 1 a is only andeuntungsweise shown, as the hose pad body 8 is led around saddle-like the face profile of the patient subsequent over the nose backs. The contact pressure of the hose pad body 8 in the range of the nose back can become on advantageous manner by the stiffening element 3 affected, as the here andeuntungsweise outlined nose back width  $n$  becomes defined fixed by the stiffening element 3. Thereby avoided becomes that the nose back range of the patient becomes over the hose pad body 8 in unpleasant manner strong compressed. By the combination of hose body 8 and stiffening element 3 will it on advantageous manner possible to reach a particularly high inertial comfort as well as an high tightness of the masque since the hose pad body 8 before edition on the face-flat of the patient already exhibits corresponding shape to a large extent into one the face outline of the patient. The combination of reinforcement body 3 and hose pad body 8 can find also independent from the integral formation of mask basis body 1 and front edition element 2 application.

[0034] In Fig. 2 here is a preferable embodiment of the reinforcement element 3 shown, that both one the face outline of the patient in the range of the nose adapted, and/or, adaptable portion 19 as well as a portion 20 adapted to the front outline of the patient exhibits.

[0035] The two portions 19, 20 are 22 coupled with one another over legs 21. The stiffening element 3 is here formed from a thermodeformable plastic material, which becomes common adapted with a corresponding mask basis body with integral front edition element at the patients. After cooling the corresponding plastic material off the stiffening element 3 maintains it the individual given form durable. The stiffening element 3 can do bedarfsweise of the mask basis body 1 and the front edition element 2 (see, for this Fig. 1a) remote will become and into a new corresponding mask basis body inserted, so that this essentially receives the same shape as the original mask bodies. By those here illustrated embodiment of the reinforcement element 3 will it possible to co-ordinate in particular the high level of the front edition element and the mask basis body 1 exact so that the corresponding individual preformed breathing mask already exhibits to a large extent its face outline corresponding shape before putting on on the face of the patient.

[0036] Alternative one to in Fig. 2 described embodiment of the frame-like formed reinforcement element 3 is it also possible, this for example from a wire material to finished, as in Fig. 3a simplified indicated. Here a not corrosive steel plant material becomes preferably used, which becomes bent over corresponding bending tools into the desired shape. This by a hook formed stiffening element 3 can then, as in Fig. 3b indicated, with the mask basis body 1 and/or, with its sealing structure coupled become. Preferably the mask basis body 1 points, and/or, the sealing structure 8, 9 corresponding recesses 11 up, into which the stiffening element can become 3 inserted. With here in Fig. 3b andentungsweise represented sealing structure is only the seal structure range shown led across the nose back of the patient.

[0037] In Fig. 4 is an other preferable embodiment of a sealing structure for a breathing mask shown, which exhibits a face sealing rim 9 here, which runs out to an extremely thin sealing rim point s. The wall-thick of the face sealing rim 9 increases gradual to a root portion of the face sealing rim. To the outer region of the face sealing rim 9 a pad body is 23 formed, which is here formed from a gel-like cured material - here silicone rubber with low degree of crosslinking - . This pad body 23 supports the mask basis body 1 common with the sealing lip 9 on the face of the patient off. With that illustrated embodiment is the mask basis body 1 separate 24 formed of the sealing structure here. The sealing structure is similar already as with the preceding described embodiments over a stiffening element 3 spatial shape preformed corresponding into one the respective face outline of the patient. It is also possible to train the sealing structure 24 shown here integral with the mask basis body 1. The outer region of the pad body 23 is with a skin layer coated, one gluing the pad body 23 to at the face surface of the patient prevented. The surface of this skin layer exhibits here a pre-determined including-like micro roughness.

[0038] In Fig. 5 is an other embodiment of a sealing structure 24 for a breathing mask shown, which likewise exhibits itself here inward an extending thin running out face sealing rim 9 essentially radial of the outer region of the breathing mask. The curvature process of the face sealing rim 9 in the cutting plane shown (plane pi in Fig. 1 A) is in an such a manner selected that the sealing lip comparatively good can adapt to the profile of the patient. The sealing structure 24 and the mask basis body 1 are here formed from different materials. Like that the sealing structure from a silicone material and the mask basis body from a thermoplastic plastic material are formed with the illustrated embodiment. The mask basis body 1 is moulded on in a particular forming tool to the sealing rim structure formed in the frame of a preceding silicone spraying step more immediate, whereby an essentially indissoluble and gap-free connection between the sealing structure becomes 24 and the mask basis body achieved. With the illustrated embodiment a circumferential land area is 25 provided in the range of the transition point between the sealing structure 24 and the mask basis body, over which the strength of the connection between mask basis bodies and sealing structure 24 is still continued to improve.

[0039] The deformation behavior of the sealing structure 24 becomes by a defined design of the wall thickness of the face sealing rim 9 as well as to it subsequent, to the mask basis body 1 continuing wall section 26 defined affected. Further numerous integral 24 bars formed with the sealing structure are 27 provided, their length and wall thickness likewise the deformation behavior of the sealing structure 24 defined affected. Although is provided with that illustrated embodiment no stiffening element here, it can also possible be attained with this seal variant by means of the reinforcement element a still more individual adaptation to the face outline of the patient.

[0040] Fig. 6 is an other preferable embodiment of a sealing structure 24 shown, which likewise exhibits itself here a hose pad body 8 and a radial inward extending face sealing rim 9. The wall both the face sealing rim 9 and the hose pad body 8 is here such a defined thick and/or, thin walled formed that the sealing structure receives a mechanism favourable regarding a particularly uniform face surface pressure. By the thin walled portions of the sealing lip 9 and the hose pad body 8 the sealing structure uniform can match the contour of the face of the patient. The hose pad body 8 is bottom application of a mandrel formed, which was released from form over an original opening formed between two flank sections 28, 29. The two flank sections 28, 29 are bonded with one another. Around defined positioning of the two flank sections 28, 29 to each other to obtained, are here corresponding profiles, for example a Nu/Feder profile 30 provided. The joint 30 formed between the two flank sections 28, 29 becomes by an edge of photograph 31 of the mask basis body 1 spread and are not more recognizable and besides, in particular thereby from the outside during the cure of an adhesive material effective protected.

[0041] In Fig. 7 is an other preferable embodiment of a sealing structure for a breathing mask shown, the similar, as already in connection with Fig. 4 described sealing structure a running out face sealing rim 9 thin to the face-flat of the patient exhibits. This face sealing rim 9 exhibits a comparatively high load-carrying capacity. Those the face-flat of the patient directed outside of the face sealing rim 9 is 23 coated to the majority with a pad body, which is formed from an elastomeric material with low degree of crosslinking (gel material). The outside of this pad body 23 is 33 coated with a including-like rough thin skin layer. This thin skin layer 33 is in accordance with, one particularly preferable embodiment of the invention from an elastomeric material, in particular likewise silicone material with higher degree of crosslinking formed. Thereby will it possible to deform the gel body without that at its outside rippling/crinkling folds arise. The cross section of the sealing structure 24 is in an such a manner selected that a part of the 23 rebellion forces introduced over

the thin skin layer 33 in the pad body is passed immediately into a root portion 24 of the face sealing rim 9 from here into the mask basis body 1. The mask basis body is here with that illustrated embodiment with the sealing structure 24 over a groove/a leather/spring structure bonded. An inner adding place 34 between the mask basis body 1 and the sealing structure 24 is by a nose sealed formed to the sealing structure 24.

[0042] In Fig. 8 is an other preferable embodiment of a sealing structure 24 shown, which likewise exhibits here a hose pad body 8 with integral formed face sealing rim 9. At the hose pad body 8 at least two thin walled portions 36, 37 extending over the whole periphery of the sealing structure are provided, becomes formed by which a tilting zone, over which the face sealing rim 9 tendentious first with their point range 1 to the face-flat of the patient urged become. The remaining portion of the hose pad body 8 is comparatively thick walled formed. The hose pad body 8 becomes here also manufactured with that illustrated embodiment using a form core element, which is released from form over a here andeutungsweise represented joint 38. In the range of the joint 38 the corresponding adjacent portions are 28, 29 bonded with one another. A defined positioning of the two portions 28, 29 becomes also here, like already in connection with Fig. 6 described, by a corresponding profile achieved.

[0043] The hose pad body 8, and/or, the entire sealing structure 24 is here formed from an extreme soft silicone rubber material, which adapts to bottom comparatively small deformation forces to the face outline of the patient high elastically. The high sealing effect of this sealing structure becomes achieved by the fact that over the here realized hinge mechanism over the face tracking forces achieved becomes that the point range s of the face sealing rim 9 continuous matches the contour of the Gesichtsoberfläche of the patient. The mask basis body 1 is 24 bonded with the illustrated embodiment over a corresponding seamed joint place 40 with the sealing structure. If necessary, also a rolling bellows-like compliance of the sealing structure can become realized.

[0044] Bottom reference on the Fig. 9a to 9e becomes the subsequent manufacturing process of a breathing mask described, which exhibits a sealing structure with an air cushion, formed from an elastomeric material, as well as a mask basis body formed from a thermoplastic plastic material.

[0045] As in Fig. 9a shown, becomes first for this a forming tool arrangement provided, those the execution of a first manufacturing step the exclusive mould space limited required to the formation of the sealing structure 24. This Werkzeuganordnung covers here a bottom die I, a mask core II, a form upper die III and an air cushion core IV.

[0046] Into such a limited mould space a silicone material becomes injected. After this silicone material bottom formation of the sealing structure is 24 cured, the form upper tool becomes 3 removed.

[0047] The sealing structure remains further in the lower forming tool. Also the two mandrels II and IV do not become from the sealing structure 24 remote, like this in Fig. 9b shown is.

[0048] As in Fig. 9c shown, becomes now an other form upper tool V on the arrangement after Fig. 9b fitted. The form upper tool V limited common with the Formkem II and a part of the sealing structure a mould space planned formed first to the formation of the mask basis body. Into this mould space now likewise a plastic material, in particular a thermoplastic plastic material injected, becomes which is received with the sealing structure 24 an intimate connection.

[0049] After confirming this plastic material the form upper tool becomes V removed. Now the sealing structure 24 with the moulded on mask basis body can become 1 from the bottom die I removed.

[0050] Releasing the air cushion core and the mandrel II from form made manual if necessary, with the help of compressed air. The high own elasticity of the sealing structure 24 allowed also with the here present large rear cut a simple releasing from form.

[0051] With that illustrated embodiment first the mandrel II is only then released from form here and the air cushion form core IV. Here one receives in Fig. 9e represented masque. The here still open, circumferential releasing from form gap S can become now bottom aid of an adhesive closed.